ULTRASONIC PROBE VOLUME COMPENSATION SYSTEM

This invention relates to medical diagnostic imaging systems and, in particular, to fluid filled probes for three dimensional imaging with ultrasonic diagnostic imaging systems.

Ultrasonic probes always benefit from a good acoustic path between the transducer and the patient's body. With static probes in which the transducer does not move, the transducer is covered with an acoustic window that is highly transmissive of ultrasound, generally a rubber-like material. The acoustic path to the body is completed with an acoustic gel between the acoustic window and the skin of the patient, which prevents air and air bubbles from obstructing or interfering with the passage of acoustic energy into and out of the body.

Mechanical probes have been in use for many years in which the transducer is oscillated to sweep a beam of ultrasound through the body for imaging. The first mechanical probes employed single element transducers which were oscillated in a fluid bath that provided acoustic coupling from the transducer element to the acoustic window. The acoustic gel would then couple the ultrasound energy between the acoustic window and the body. This same approach was used with oscillating annular array transducers, in which the annular array was electronically focused as its beam was swept through an image plane of the patient.

In recent years the use of mechanical single element probes has declined as static array probes with electronic beam steering have replaced them. But with the recent advent of live three dimensional ultrasonic imaging, mechanical probes have begun to

appear which oscillate an array of transducers that electronically steers beams as the array is moved. The array transducer can be electronically controlled to steer beams in the azimuth direction as the

5   mechanical oscillation moves the array in the elevation direction, thereby transmitting and acquiring ultrasonic energy from a volumetric region rather than just a plane. In essence, the array electronically scans a plane and the plane is

10   mechanically swept through the volume being imaged. These three dimensional mechanical array probes, like their single element ancestors, need a means for coupling ultrasonic energy from the moving transducer to the acoustic window. Like their predecessors, a

15   fluid bath is the most common and convenient coupling means.

         With fluid bath probes come the familiar challenges which fluids present. Fluid-filled probes can leak and can develop air bubbles in the fluid

20   which can interfere with the acoustic path. These problems are often the result of expansion and contraction of the fluid and probe components with changes in temperature and pressure. A probe shipped by airplane can be subject to low pressures and

25   temperatures during transit, whereas a probe left in an automobile in the sun can be subject to high temperatures. Accordingly it is desirable to provide a means for accommodating such expansion and contraction within the probe itself so as to prevent

30   the development of fluid leakage and air bubbles in the acoustic path of the probe.

         In accordance with the principles of the present invention a fluid-filled ultrasound probe with a moving transducer is described which includes a

35   volume compensation system that accommodates changes

in fluid volume with changes in temperature or
pressure. The volume compensation system includes a
thin-walled balloon made of a high performance
thermoplastic material which is coupled to the fluid

5   chamber for the transducer. At nominal temperatures
and pressures the balloon is partially collapsed so
that it will respond to increases or decreases in
pressure or temperature by collapsing or expanding
without reaching its expansion limit. The

10   thermoplastic material enables the balloon wall to be
very thin which offers little resistance to the
filling and emptying of the balloon with changes in
fluid temperature or pressure. In accordance with a
further aspect of the present invention, the thin-

15   walled balloon has a low permeability to the fluid
which fills the fluid chamber of the probe. A
desirable balloon material should also exhibit high
integrity in terms of tear strength, burst strength,
and puncture strength.

20   In the drawings:
FIGURE 1 illustrates a typical intracavity
ultrasound probe of the prior art.
FIGURE 2 illustrates a partially cut-away side
view of an intracavity probe for three dimensional

25   imaging of the present invention.
FIGURE 3 is a perspective view of the tip
assembly of a 3D intracavity probe of the present
invention.
FIGURE 4 is a perspective view of a volume

30   compensation balloon constructed in accordance with
the principles of the present invention.
Referring first to FIGURE 1, a typical IVT
intracavity ultrasound probe of the prior art is
shown. This probe includes a shaft portion 12 of

35   about 6.6 inches (16.7 cm) in length and one inch

(2.54 cm) in diameter which is inserted into a body
cavity during use. The ultrasound transducer is
located in the distal tip 14 of the shaft. In this
probe the transducer is a static curved array

5   transducer which is able to scan a planar sector
around the tip of the probe. The probe is grasped
and manipulated by a handle 16 during use. At the
end of the handle is a strain relief 18 for a cable
20 which extends about 3-7 feet and terminates at a

10   connector 22 which couples the probe to an ultrasound
system. A typical two dimensional imaging IVT probe
such as the one shown in FIGURE 1 may have a shaft
and handle which is 12 inches in length and weigh
about 48 ounces (150 grams) including the cable 20

15   and the connector 22.
              Referring now to FIGURE 2, an intracavity
ultrasound probe 30 for three dimensional imaging
which is constructed in accordance with the present
invention is shown. The probe 30 includes a handle

20   section 36 by which the user holds the probe for
manipulation during use. At the rear of the handle
is a strain relief 18 for the probe cable (not
shown). Extending from the forward end of the handle
36 is the shaft 32 of the probe which terminates in a

25   dome-shaped acoustic window 34 at the distal end
through which ultrasound is transmitted and received
during imaging. Contained within the distal end of
the shaft is a transducer mount assembly 40 which is
also shown in the uncovered view of the tip assembly

30   of FIGURE 3. A convex curved array transducer 46 is
attached to a transducer cradle 48 at the distal end
of the assembly 40. The transducer cradle 48 is
pivotally mounted so it can be rocked back and forth
in the distal end of the probe and thereby sweep an

35   image plane through a volumetric region in front of

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the probe. The transducer cradle 48 is rocked by an oscillating drive shaft 50 which extends from a motor and shaft encoder in the handle 36 to the transducer mount assembly 40. The drive shaft extends through an isolation tube 52 in the shaft which serves to isolate the moving drive shaft from the electrical conductors and volume compensation balloon 44 located in the shaft proximal the transducer mount assembly 40. The construction and operation of the rocking mechanism for the transducer cradle 48 is more fully described in concurrently filed US patent application serial number 60/559,321, entitled ULTRASONIC INTRACAVITY PROBE FOR 3D IMAGING, the contents of which are incorporated herein by reference. The echo signals acquired by the transducer array 46 are beamformed, detected, and rendered by the ultrasound system to form a three dimensional image of the volumetric region scanned by the probe.

Because ultrasonic energy does not efficiently pass through air, the array transducer 46 is surrounded by a liquid which is transmissive of ultrasound and closely matches the acoustic impedance of the body which is approximately that of water. The liquid is contained within a fluid chamber 42 inside the transducer mount assembly 40 which also contains the array transducer 46. Water-based, oil-based, and synthetic polymeric liquids may be used. In a constructed embodiment silicone oil is used as the acoustic coupling fluid in the transducer fluid chamber. Further details of the fluid chamber of the embodiment of FIGURE 2 may be found in concurrently filed US patent application serial number 60/559,390, entitled ULTRASOUND PROBE WITH MULTIPLE FLUID CHAMBERS, the contents of which are incorporated herein by reference.

In accordance with the principles of the present
invention a thin-walled balloon 44 of high
performance thermoplastic is coupled to be in fluidic
communication with the transducer fluid chamber 42.
The balloon is shown in perspective in FIGURE 4. In
the embodiment of FIGURE 4 the balloon 44 is made of
a PET polymer which can be made very thin and
exhibits a low permeability to fluids such as
silicone oil. Silicone oil is a good fluid for
probes because it has a low coefficient of expansion
β with temperature. As a result, the change in
volume of the fluid with temperature changes ($\Delta V = \beta V_o \Delta T$) is relatively low. In a constructed embodiment
of the present invention the probe was designed to be
able to accommodate volume changes ΔV of the fluid
over a temperature range of -40°C to +70°C. Silicone
oil, which is available from Dow Corning Corp. of
Midland Michigan was found to exhibit favorable
expansion characteristics with coefficients of around
0.00065/°C.

In the constructed embodiment in which the
balloon 44 was made of a high performance
thermoplastic, the balloon wall thickness was
approximately 0.6 mil. Wall thicknesses of 5-50
microns (0.0002-0.002 inches) have been found to
exhibit the desired compliance ($\Delta P/\Delta V$) while at the
same time exhibiting the desired low permeability (p)
to fluids. Partially filled balloons of the above
wall thickness have been found to offer little
resistance to filling and emptying, with compliances
of less than 2 psi per ml. The permeability of the
high performance thermoplastic material has been
found to be an order of magnitude better than typical
elastomers, with the permeation rate p per unit
thickness generally less than 1.0 and usually in the

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range of 0.1 to 0.2 $cm^3 \cdot mm/m^2 \cdot day \cdot atm$ (for gas
permeability). It should be noted that silicone
fluids are known to aggressively permeate many
plastics which are impermeable to most other fluids.

5   The volume compensation balloon should also
exhibit good thermal stability. High performance
thermoplastics such as PET are used below the glass
transition temperature Tg of the material.
Elastomeric balloons have a low glass transition

10   temperature, usually in the range of −10°C to −80°C
and consequently are always highly elastic and
rubber-like at their intended operating temperatures,
e.g., room temperature. Elastomeric balloons also
undesirably have a higher ΔP vs ΔV and will become

15   stiff and resist collapsing in colder temperatures.
A volume compensation balloon of the present
invention should be thermally stable so that the
compliance does not deteriorate throughout the
intended temperature range of use.

20   Elastomers, being highly elastic by design, will
stretch considerably and can usually be stretched in
excess of 100% and still return to the original size
and shape. A high performance thermoplastic balloon
of the present invention is rigid and can generally

25   only be stretched about 2%-7% before yielding. When
excessively stretched the balloon will not return to
its original size and shape but will experience
plastic deformation. A constructed embodiment
exhibited a coefficient of expansion of only

30   ~0.00013/°C.
A high performance thermoplastic balloon should
also exhibit a high burst strength. A constructed
embodiment exhibited a burst strength pressure
resistance of 18 atmospheres.

In summary, the factors that should be considered when choosing a balloon material are the ability to fabricate a thin-walled balloon since stiffness of the balloon is principally controlled by wall thickness. The balloon should be rigid yet compliant due to the thin wall design. The material should also exhibit low permeability to the acoustic fluid; good thermal stability so that the balloon will not become stiff at low temperatures; and good integrity in terms of burst strength, tear strength, and puncture resistance.

The fluid chamber 42 in the transducer mount assembly 40 of the embodiment of FIGURE 4 has a fluid capacity of 6 ml. The capacity of the volume compensation balloon 44 is chosen in consideration of this fluid volume, and in a constructed embodiment a balloon with a fluid capacity of 0.8 ml was used. The balloon 44 is adhesively attached to a stainless steel fitting 62 at one end of the balloon and to another threaded fitting 54 at the other end. The fitting 62 is then adhesively attached to a port 64 at the proximal end of the transducer mount assembly which connects to the fluid chamber. The fluid is put into the chamber through a fill port also located on the proximal end of the transducer mount assembly 40. The balloon is partially compressed to about half its nominal volume during the filling process. As fluid is applied to the chamber the air in the chamber is forced into the balloon and out the proximal end of the balloon through the threaded fitting 54 until the chamber and the compressed balloon are completely filled with fluid and all of the air in the chamber and balloon has been forced out through the balloon fitting 54. A screw 58 is then screwed into the threaded fitting 54 and the

fill port closed. The compression of the balloon is then released. In a constructed embodiment the balloon with a total fluid capacity of 0.8 ml was filled with approximately 0.3 ml of fluid. Should

5   the fluid volume thereafter decrease at lower temperatures fluid from the balloon will flow into the probe fluid chamber with the low stiffness (high compliance) of the balloon allowing this to happen with little resistance, thereby maintaining the fluid

10   pressure substantially constant in the probe. Should the fluid volume increase with increasing temperature, fluid will flow from the fluid chamber into the balloon and the balloon will begin to approach its uncollapsed shape with the ingress of

15   more fluid, again maintaining the pressure within the chamber. The substantially constant pressure of the fluid will thus put no additional stresses on the seals of the fluid chamber. The probe will be able to be transported and used in a wide range of

20   temperatures without the occurrence of leaks or the development of bubbles which would reduce the performance of the probe.